INSTRUCTIONS FOR PREPARING A GCRC SUPPLEMENTAL APPLICATION
- April 2, 2002 -

I. TYPES OF SUPPLEMENTS

Funded General Clinical Research Centers (GCRCs) may request supplemental funds. In general, requests for small increases in the budget may be handled administratively without peer review (an administrative supplement). Larger requests--including requests for new satellites, resources, or cores (e.g., informatics or imaging cores)--will be peer reviewed as competing supplements. In all cases, applicants must consult with staff in the NCRR Division of Clinical Research (DCR) before submitting the supplemental request.

II. COMPETING SUPPLEMENTS

Occasionally, GCRC supplements are solicited by NCRR, and the guidelines for those will be described in a Request for Applications or Program Announcement. All text below refers to unsolicited competing supplements.

A. Competing supplemental requests will not be accepted without approval, given at least six weeks prior to the anticipated submission, by the DCR. The format and review of supplemental grant applications are similar to those of new and renewal GCRC grant applications, except that the information to be included (projects, biographical sketches, tables, etc.) may be limited to that required to justify the items requested in the supplemental application. The deadline receipt dates for supplemental applications are the same as those for new and renewal GCRC applications. Site visits are not usually required for supplemental applications, unless they are very large or require additional assessment of GCRC resources.

B. When preparing a competing supplemental application, follow the format as prescribed for Parts I - IV on pages Supplement I-6 and Supplement I-7 of the Division of Clinical Research Guidelines. Include all specified "Resources and Environment" sections (e.g., Patient Care; Physical Resources and Utilization; Data and Safety Monitoring Plan), even if the text in some of these sections is extremely brief. As specified in the PHS 398 instructions, the supplemental application must be complete so that it can be evaluated by a peer-review committee, without reference to the "parent" GCRC grant application.

C. Clearly justify the need for the requested new core or resource. For example, describe the accomplishments of the "parent" GCRC without the core, and the projected impact of the new core. Identify the investigators who will use the new core, and indicate the amounts and sources of their peer-reviewed support. The investigators should span diverse disciplines and have independent peer-reviewed support. Provide information (see section I below) about the protocols and/or investigators that will utilize the new

core either in the application or in an appendix to the application. A core might serve, for example, clinical and/or biostatistical and/or laboratory-only protocols. A core that only supports a few investigators requires special justification.

D. If similar resources already exist at the institution, explain how the proposed GCRC facility will enhance or complement them. Explain how the proposed core will bring "added value" to the entire GCRC, rather than benefiting only a few investigators. Describe or estimate any cost savings the core might achieve over individual investigator-funded operations. Indicate the amount of institutional support that will be provided for this core. If none, this should be clearly stated.

E. Clearly link major resource requests directly to protocols. This includes personnel, space, equipment, software, etc. This could be accomplished using tables, and it is critical for assessing budget requests. Justify budget requests with realistic workload assumptions in support of specific protocols. If anticipated use of resources by investigators at other institutions is cited as a justification for the need for resources, letters documenting the proposed use by, and any financial arrangements with, these parties should be included in the application. Discuss any anticipated generation of program income.

F. Clearly describe how and by whom resources will be allocated and prioritized. Include provisions for supporting junior investigators and pilot projects, as well as established, funded investigators. These provisions may include CReFF funds and other mechanisms for ensuring that junior investigators have adequate access to the proposed core facility or other requested resources.

G. Describe how the resource will be supported. If appropriate, include a plan for cost sharing with, or charge-back of core resources to, investigators. Define rules for providing core resources that are already funded through an investigator=s individual grant. In most cases, support for primary outcome measures and data collection and analysis should come from investigators' individual grants. If the proposed core will save costs or provide a better service or other added value, funded investigators should generally provide funds via charge-backs for part or all of the costs of the service. The plan should provide standardized rules that are fair to all investigators, while encouraging new investigators and pilot projects.

H. Describe an administration for the core that is responsible to the GCRC Advisory Committee (GAC) and Program Director. If the core contains facilities or personnel that are shared with non-GCRC investigators, clearly describe how these resources will be administered, while safeguarding against use of GCRC funds for non-GCRC activities.

I. Research projects that have already received GAC review and approval should make up the bulk of the proposed scientific activity for the new core. Pending protocols, or

investigative groups who have expressed interest in using the new core but without GAC-approved protocols, may be described in the application, but they will not be given major weight in the review process. Pilot projects, designed to generate data for peer-reviewed grant applications, are encouraged, and the means of prioritizing them should be clearly presented. Research protocols included in the application should follow the instructions and include all information requested on pages Supplement I-28 and Supplement I-29 of the Division of Clinical Research Guidelines under "Unpresented Protocols."

J. For molecular biology/genomics cores, describe the informatics and biostatistical support that will be required. For example, a genotyping or gene expression core is likely to require sophisticated data management and analysis. The availability and suitability of informatics and biostatistical resources should be described, and letters of collaboration from informatics staff should be included in the application. If these resources are not already available, they should be requested and justified in the application.

K. For informatics cores, describe, or include plans to develop, a manual of operations. The existing or proposed manual should include standard operating procedures for establishing and maintaining access/security; system administration; and data backup, disaster recovery, and archiving. There should be institutional support of GCRC staff desktop computers, so that the core spends most of its resources supporting and training investigators. If this institutional support is not available, this should be clearly discussed.

L. For bioinformatics cores, describe the relationship between the proposed bioinformatics core and the existing informatics core. Explain how they will interact in terms of overall data management for protocols. If resources are requested that will provide services/training for other GCRCs, provide data on which centers will use the resource and the projected utilization. If resources are requested to support protocols from other GCRCs, provide specific information about these protocols.